REMARKS/ARGUMENTS

The rejections presented in the Office Action dated May 28, 2009 (hereinafter Office Action) have been considered. Claims 1-26 and 67-74 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1-4, 7-14, 16-18, and 20-22 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,716,392 to *Bourgeois et al.* (hereinafter "*Bourgeois*"). Also, claims 5-6 and 23-26 are rejected based on 35 U.S.C. §103(a) as being unpatentable over the modified *Bourgeois* as applied to claims 1-4, 7-14, 16-18 and 20-22.

Independent claim 1 recites in part:

> advancing a lead introducing system through the pericardium and epicardium, and to the myocardium of the patient's heart, the lead introducing system comprising one or more myocardium penetrating components;
>
> penetrating the myocardium with the one or more myocardium penetrating components;
>
> advancing a distal portion of a lead into the myocardium using the lead introducing system, the distal portion of the lead advancing into the myocardium one or both of over and within the one or more myocardium penetrating components of the lead introducing system;

Bourgeois does not disclose advancing a lead over or within a myocardium penetrating component into myocardium. *Bourgeois* discloses a lead pulled behind a curved needle 53, the lead tethered to the needle 53 by a strand 55, as shown in *Bourgeois'* Fig. 5:

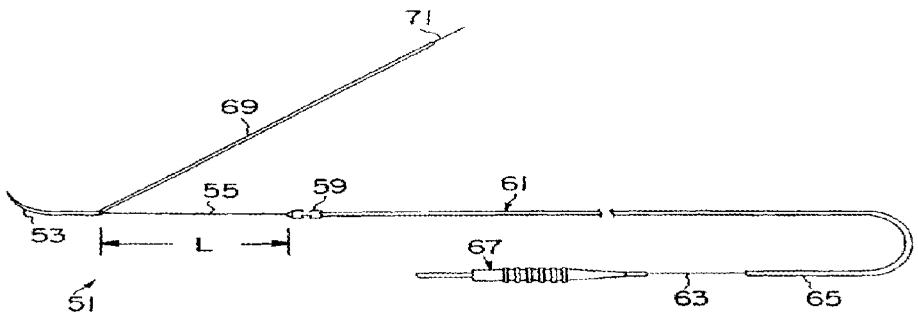


FIG. 5

Bourgeois states that the "[n]eedle 53 is then introduced through heart tissue at first location 30 and exited at second location 32. Strand 55 is then pulled from second location 32 until electrode 59 to which it is attached is pulled into the orifice at location 30" (Col. 5, Lines 35-39) as shown in Figs. 7 and 8:

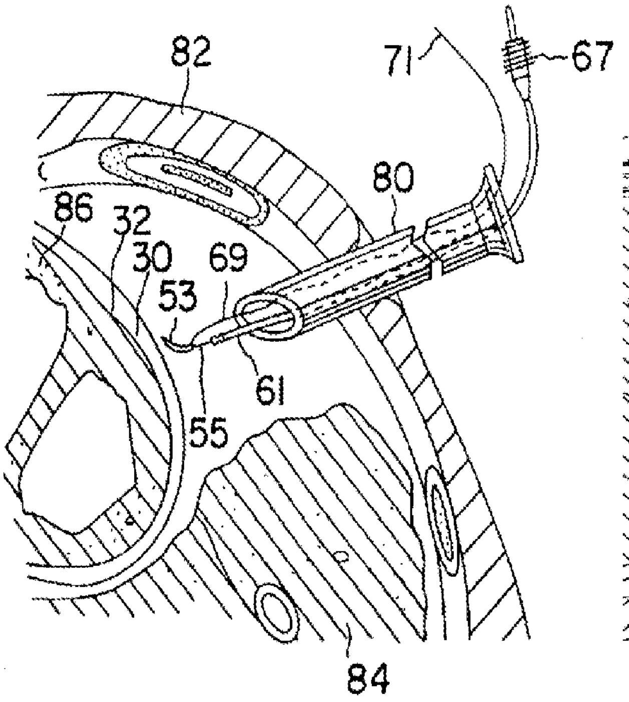


FIG. 7

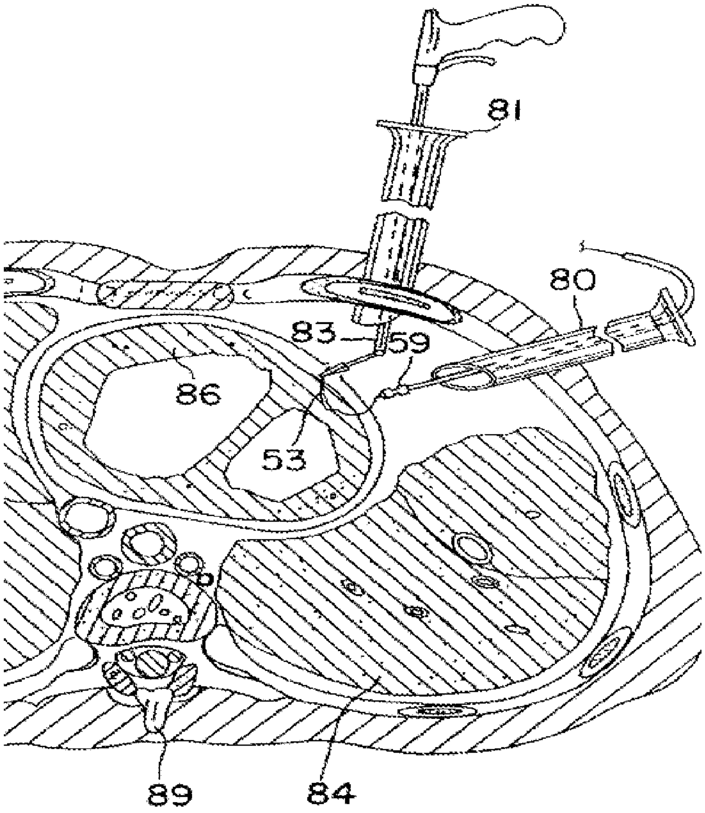


FIG. 8

As shown and described, the lead is not advanced over or within the needle 53 or strand 55. Instead, the lead is pulled behind the needle 53 and strand 55. Therefore, it would appear that *Bourgeois* is missing a teaching or suggestion corresponding to at least advancing a lead over or within a myocardium penetrating component into myocardium.

In this regard, the Office Action states:

> Bourgeois et al. teaches the device substantially as claimed but fails to teach placing the lead over the strand and needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle and strand dragging the lead to the desired location by placing the lead over the needle and strand at the desired

> location in the myocardium. Such a modification would provide the predictable results preventing the weakening or breaking of the strand when pulling the lead during implantation. (Pages 2-3).

The Applicant notes that *Bourgeois* fails to teach placing the lead over the strand and needle. Instead of providing disclosure of advancing a lead over or within a myocardium penetrating component into myocardium to account for independent claim 1, the Office Action posits why this might be done. Such a rejection would appear to be improperly based on hindsight reasoning instead of prior art teachings accounting for all elements of the invention.

Even if based on hindsight reasoning, such a modification would still not fully correspond with the independent claim. For example, claim 1 states "the distal portion of the lead advancing into the myocardium one or both of over and within the one or more myocardium penetrating components of the lead introducing system" (it is noted in claim 1 that the one or more myocardium penetrating components are advanced into the myocardium in a preceding step). Even if *Bourgeois* was modified to "plac[e] the lead over the needle and strand at the desired location in the myocardium" as proposed in the Office Action, such a modification does not constitute a "distal portion of the lead advancing into the myocardium one or both of over and within the one or more myocardium penetrating components" (claim 1). For at least this reason, *Bourgeois* as proposed to be modified, does not correspond to all elements of independent claim 1.

Moreover, one having ordinary skill in the art would not make the proposed modification. First, the modified method steps do not seem possible in the system of *Bourgeois*. The needle 53 and strand 55 appear solid and much smaller than the lead 51, such that the lead 51 could not advance within the needle 53 or strand 55. Additionally, the lead 51 itself is solid (Figs. 22-23) so it could not advance over the needle 53 or strand 55. Therefore, the proposed modification of *Bourgeois* is not feasible, and therefore not a modification that one having ordinary skill in the art would make.

Furthermore, it would appear that the proposed modification would frustrate the purpose of *Bourgeois*. The Office Action appears to propose not using the strand 55 to drag the lead 51 behind the needle 53 (e.g., the Office Action proposes “placing the lead over the needle and strand at the desired location in the myocardium” so to “prevent[] the weakening or breaking of the strand when pulling the lead during plantation”). *Bourgeois* clearly envisions that the lead be dragged behind the curved needle by use of the strand 55, which is a technique that *Bourgeois* states is less invasive. Specifically, *Bourgeois* states “Through the unique properties offered by the needle and strand together, the medical electrical lead of the present invention may be introduced into the body using a minimally invasive technique.” (Col. 4, Lines 38-42). Accordingly, *Bourgeois* clearly teaches away from any modification that would seek to reduce the role of the strand in dragging the lead behind and curved needle, rending such a modification improper.

Moreover, such a modification would change the principle of operation of *Bourgeois*’ system, which amounts to an impermissible modification under MPEP 2143.01(VI). Pulling the lead behind the curved needle using the strand is described as offering the unique properties that make the invention minimally invasive. (Col. 4, Lines 38-42). A modification deviating from this mode of operation would be impermissible as changing the principle of operation.

Regarding the proposed non-use of components of *Bourgeois’* system, the Office Action further states:

> Additionally, such a modification could also provide the predictable results of reducing or eliminating the need for the second trocar 81 and forceps 83 to anchor the lead and remove the needle, which would simplify the implantation of the lead as well as reduce the access sites in the patient's chest. Such a reduction of access sites would reduce the amount of trauma sustained by the patient. (Page 3).

The Applicant notes that the effect of such a modification rebuts the rejection. Omission of an element or step (i.e., the strand 55, second trocar 81, or forceps 83, as well as the dragging step) and retention of its function (i.e., lead implantation in myocardial tissue) is an indicia of unobviousness. (MPEP § 2144.04, section II-B entitled “ELIMINATION OF A STEP OR AN ELEMENT AND ITS FUNCTION”, citing *In re Edge*, 149 USPQ 556 (CCPA 1966)). Accordingly, the patentability of the claims over

Bourgeois is additionally evidenced by any extent that the claimed invention "would simplify the implantation of the lead" of *Bourgeois* by elimination of elements and steps. (Page 3 of the Office Action).

For each of the reasons discussed above, the Applicant respectfully submits that the proposed modification of *Bourgeois* is improper and further does not account for all elements of independent claim 1. Accordingly, the Applicant respectfully requests reconsideration and withdrawal of the rejection of this claim.

Dependent claims 5, 6, 23, and 24 each concern some variation of creating myocardial space using a dilator sheath advanced over a piercing needle. *Bourgeois* fails to teach advancing a dilator sheath over the needle 53 into myocardial tissue, and therefore further fails to teach creating space in myocardial tissue with a dilator sheath, in the manner claimed.

In addressing these claims, the Office Action states:

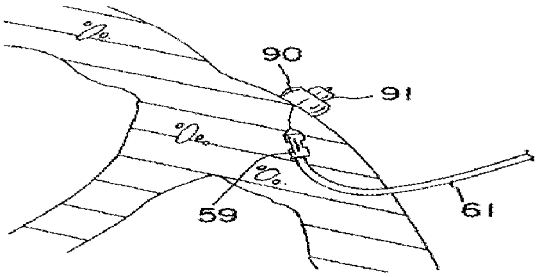
> The modified Bourgeois et al. discloses the device substantially as claimed except for the dilator or dilating sheath. It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert a dilator or dilating sheath to create space within the myocardium in order to provide the predictable results of easier implantation and maneuverability of the needle and lead to reduce the amount of tissue trauma sustained by the patient during implantation. Furthermore, it is additionally well known in the art to employ dilators or dilating sheaths. (Pages 4-5).

The Applicant notes that the claims 5, 6, 23, and 24 do not merely recite a dilator or dilating sheath. Rather, specific method steps using a dilator sheath are presented. As stated by the Office Action, "The modified Bourgeois et al. discloses the device substantially as claimed except for the dilator or dilating sheath." As such, even if dilator sheaths were known, the proposed use of a dilator sheath in the myocardium (corresponding to the claims) would appear to be completely based on hindsight reasoning instead of prior art teachings.

Moreover, *Bourgeois* uses the dragging of the lead behind the curved needle via the strand to carry out minimally invasive myocardial lead implantation. (Col. 4, Lines 38-42). Using a dilator sheath over these components to create more space in the myocardium would seem to diverge from the techniques *Bourgeois* uses to carry out minimally invasive myocardial lead implantation. It is not clear how use of a dilator sheath with the system of *Bourgeois* would "reduce the amount of tissue trauma sustained by the patient during implantation." Instead, the proposed modification would seem to exacerbate the tissue trauma *Bourgeois* is attempting to avoid.

For each of the reasons discussed above, the Applicant respectfully submits that the rejection does not account for a myocardial penetrating dilating sheath, or specific use of a dilating sheath corresponding to any of claims 5, 6, 23, and 24. Accordingly, the Applicant respectfully requests withdrawal of the rejection of these claims.

Dependent claim 14 recites placing a fixation element epicardially at or near a location at which the lead enters the myocardium. The Office Action appears to omit discussion of claim 14. Moreover, Fig. 10 of *Bourgeois* is reproduced below, showing fixation by attachment to the fixation disk 90.



F I G. 10

The attachment mechanism of *Bourgeois* is not at or near where the lead 61 enters the myocardium, as can be seen from Fig. 10. *Bourgeois* does not teach placing a fixation element epicardially at or near a location at which the lead enters the myocardium, and therefore cannot account for dependent claim 14.

Dependent claim 21 recites "the lead comprises proximal and distal ends and an open lumen defined therebetween; . . . and advancing the lead comprises passing the lead over the piercing needle and through the open lumen." The Applicant respectfully submits that the Office Action appears to omit discussion of claim 21.

The Applicant respectfully submits that it does not appear that the solid lead of *Bourgeois* has a lumen extending from the proximal end to the distal end. The absence of such a lumen would mean that the lead could not pass over the needle. As such, *Bourgeois* does not account for dependent claim 21.

Dependent claim 25 concerns using a stylet that stiffens the lead for advancement within a dilating catheter. The Office Action appears to omit discussion of claim 25. Even so, the Applicant respectfully submits that *Bourgeois* fails to disclose use of a stylet in the manner claimed in dependent claim 25.

Dependent claims 2-26, which depend from independent claim 1, were also rejected under 35 U.S.C. §103(a) as being unpatentable over *Bourgeois*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2-26 are also not properly obvious in view of *Bourgeois*.

For each of the reasons discussed above, the Applicant respectfully requests withdrawal of the obviousness-type rejections of claims 1-26 and notification that these claims are in condition for allowance.

To the extent that the Applicant has not responded to any characterization in the Office Action of the asserted art or of the Applicant's claimed subject matter, or to any application in the Office Action of the asserted art to any claimed subject matter, the Applicant wishes to make clear for the record that any such lack of response should not be interpreted as an acquiescence to such characterizations or applications. A detailed discussion of each of the Office Action's characterizations, or any other assertions or statements beyond that provided above is unnecessary in view of the present response. The

Applicant reserves the right to address in detail any such assertions or statements in the future.

The Applicant respectfully submits that the application is in condition for allowance, timely notification of which is kindly requested. Authorization is given to charge Deposit Account No. 50-3581 (GUID.077PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

HOLLINGSWORTH & FUNK, LLC
8009 34th Avenue South, Suite 125
Minneapolis, MN 55425
952.232.6725

Date: July 27, 2009 By: /Paul Sherburne/

Paul Sherburne
Reg. No. 57,843